Opened May 2009
Grew from 60 pts/day to 80 pts/day by early 2011
TOMO FDA APPROVED February 2011
Installed tomo April 2011…2 nd site in US to use clinically
Grew rapidly to about 100-120 pts/day
To date have done over 22,000 tomo cases

Why Tomosynthesis?
• A major factor contributing to the limited performance of mammography is the tissue superimposition that is created by the overlap of normal breast structures in a two-dimensional mammographic projection.
• These overlapping structures can obscure a lesion making it more difficult to perceive or rendering it completely mammographically occult.

Selenia Dimensions
3D Principle of Operation

- X-ray tube moves in an arc across the breast
- A series of low dose images are acquired from different angles
- Total dose approximately the same as one 2D mammogram
- Projection images are reconstructed into 1 mm slices

Arc of motion of x-ray tube, showing individual exposures

Compression Paddle
Compressed Breast
Detector Housing

Reconstructed Slices

TOMOSYNTHESIS
Started by offering to women with dense to moderately dense breasts AND to women requesting tomo

Wait times excessive

Added 2nd tomo unit in September 2011

3rd unit ordered for satellite office

**IMPLEMENTATION**

**Why Dense Breasts**

- Initially thought only significant benefit to dense breasts
- Later discovered benefit for fatty breasts as well

**SCREENING:**

- Combo mode (FDA mandated)
- 3D set obtained first, 2D set last
- Same compression and positioning as 2D
- CC and MLO views….some lesions still seen

**PROTOCOL**
DIAGNOSTIC:
- Can use as needed…2D screening will get tomo only call back
- Tomo screening: usually DO NOT do spot compression images…go straight to US for mass or distortion (SPOT TOMO…using for areas where compression might not be optimal)
- Still do spot mag for calcifications

PROTOCOL

• Radiation dose is similar to film screen mammography (COMBO MODE)
  - 2D~1.2 mGy
  - 3D~1.45 mGy
  - Combo ~2.65 mGy
  - Screen/Film (ACRIN) ~2.0 mGy average

**** based on ACR phantom ****
A 3D image set is obtained, with a 2D image reconstructed from that data set. This will effectively decrease radiation dose by 50%. Used for guide in viewing the 3D image set and for comparison to old mammograms. ACCENTUATES distortions and calcifications. Does NOT accentuate smooth masses.

How does it work?

Perform a standard tomosynthesis scan (existing system)

Reconstruct tomosynthesis slices (existing system)

~60 Tomosynthesis Slices

Reconstruction Algorithm

15 Projection Images

*C-view Synthesized 2D Image

~60 Tomosynthesis Slices

C-view Synthesized 2D Image

How does it work?

Perform a standard tomosynthesis scan (existing system)

Reconstruct tomosynthesis slices (existing system)

Synthesize 2D image (C-View)

Similar to Maximum Intensity Projection (MIP) as done with MRI images

*Not approved for sale in the United States
CALCIFICATIONS with C-VIEW examples
DISTORTIONS with C-VIEW

example
1/15 readers recalled

mean POM: 14.4%
(probability of malignancy)
Rationale for 3D plus *C-View

- The advantage of two-view tomosynthesis while reducing dose and capitalizing on the benefits of 3D

- Value of a 2-dimensional “summary” image:
  - Assessment of side to side symmetry
  - Assessment of interval change
  - Detection of calcifications
  - Recognition of the distributional aspect of features (particularly calcifications)

*Not approved for sale in the United States
These cases illustrate one of the greatest benefits of tomosynthesis: the elimination of superimposed normal tissues.
This case illustrates the ability of tomo, by eliminating superimposed tissues, to show a small cancer NOT VISIBLE on the 2D mammogram. The cancer is also not seen on additional spot compression images...so we now RARELY do spot compression views.
This case illustrates how the 1mm slice allows visualization of distortion MUCH BETTER, even in a relatively fatty breast. This allows more accurate and complete workups.

MULTIFOCAL IDC
This is another case of cancer seen ONLY WITH TOMO, and in this case, really only well seen on the MLO TOMO VIEW. On our screen, a scrollbar displays the slice number and indicates position, so even if only seen on one view, it can still be localized.

INVASIVE DUCTAL CA

Routine screening
Because this was a distortion with linear calcifications extending anteriorly, excision was done, showing no evidence of malignancy.

RADIAL SCAR
The Oslo Tomosynthesis Screening Trial (Dr Skaane)

12,631 patients...compared 2D alone to 2D +3D over a 13 month period

OSLO STUDY

40% increase in detection of invasive cancers
27% increase in detection of ALL cancers (invasive and in situ)

OSLO STUDY FINDINGS
- Decrease mammo call backs (decreased by 40% at our site)
- Ultrasound call back unchanged (fewer call backs for superimposed tissues, but are finding more REAL lesions)
- Increase PPV (increased by about 35%)
- BR3 decreased by 2% for entire practice

TOMO BENEFITS

Better able to determine multifocality
Often can see an associated mass (with calcs), which might be occult on 2D...prompting search with ultrasound for invasive component

MORE BENEFITS
Stopped using mole markers and nipple markers
Stopped having to work up skin calcs, moles, vascular calcs
Can localize even when only seen on one view (using the scrollbar)…less time wasted searching with additional images

OTHER BENEFITS

SUMMARY

What that MEANS is that each callback has a MUCH HIGHER probability of being REAL….must be more diligent with callbacks as we KNOW we should find something with ultrasound
SUMMARY

Fewer mammo callbacks = schedule freed up for more screenings and for more “necessary” workups
techs spend much less time searching for a lesion with the smaller spot compression paddle

LESSRADIATIONDOSEFORTHEPOPULATION

FINAL SUMMARY

I think the major strength of 3D is for screening…increased confidence in BR1 and BR2, better detection of subtle distortion, small masses
Increased confidence that a callback will be an actionable finding

THANKS FOR YOUR ATTENTION
The radiation dose for combo mode (2D plus 3D) is:

- 1. 1.45 mGy
- 2. 2.65 mGy
- 3. 4.85 mGy
- 4. 8.85 mGy
- 5. 10.65 mGy

**ANSWER**

2.65 mGy


One of the major benefits of 3D imaging is:

- 1. Lower radiation dose per case
- 2. Better visualization of calcifications
- 3. Less compression
- 4. Elimination of superimposed normal tissues
- 5. Easier positioning
ANSWER
Elimination of superimposed normal tissues
Kopans. Breast Imaging, 3rd edition. Lippincott Williams and Wilkins

The one thing that C-View would NOT be helpful for would be:

0% 1. Decreased radiation dose by about 50%
0% 2. Better visualization of smooth/benign masses
0% 3. Accentuation of distortions and calcifications
0% 4. Comparison to prior 2D exams
0% 5. Guide for viewing the 3D image set

ANSWER
Better visualization of smooth/benign masses

http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/RadiologicalDevicesPanel/UCM325901.pdf
The major findings of the Oslo study regarding 2D imaging vs 2D plus 3D imaging for screening were:

0% 0% 0% 0% 0%
1. There were no advantages to including 3D imaging in their population
2. There was a 40% increase in the invasive cancer detection rate
3. The detection rate for noninvasive cancers fell by 10%
4. 3D imaging was only helpful in denser breasts
5. The call back rate for additional imaging increased, due to better visualization, by 25%

ANSWER
There was a 40% increase in the invasive cancer detection rate


What is the one thing we have NOT FOUND since tomosynthesis was introduced:

0% 0% 0% 0% 0%
1. Decreased call back rate for additional mammographic imaging by about 40%
2. More BR3 (probably benign) results
3. Increased cancer detection rate (40% for invasive cancers, by Oslo study)
4. Stable call back rate for ultrasound examinations
5. Increased positive predictive value for biopsies of about 35%
ANSWER
More BR3 (probably benign) results
